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HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			VAN LENTE, MICHAEL A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/586,697	ROSMAN ET AL.
	Examiner	Art Unit
	MICHAEL VAN LENTE	1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 and 26-28 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-24 and 26-28 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 July 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it is too long. Abstracts should not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.
3. A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n). See Claims 8, 13, 14 and 19.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 5 recites the limitation "the chamber" in the third line of the claim and the limitation "said female connection portion" in the last line of the claim. The antecedent basis for these limitations is not consistent with the last two lines of Claim 5 because the language of the Claim 5 preamble together with the language of Claim 4 requires that both of these limitations refer to the said "first one of the chamber portions" of the pair of adjacent chamber portions. If the term "annular wall" is to apply to both the cap and the female connection portion, clarification is needed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(b) as being anticipated by US 6,251,660 B1 to MUIR, et al. (hereinafter 'Muir').

9. As per Claim 1, Muir discloses a sampling and assay device (abstract; col. 1, ln 44-52) comprising: a chamber assembly defining at least three chambers arranged in a row, adjacent chambers along the row being separated by respective partitions (FIGS. 9, 10), wherein at least one of the chambers is capable of receiving a sample (col. 4, ln 25-29; col. 5, ln 35-38; col. 10, ln 3-7; col. 18, ln 4-8; col. 19, ln 38-40; col. 22, ln 55-57)

and at least a further two of the chambers contain reagent (col. 2, ln 36-46; col. 19, ln 26-29; col. 22, ln 33-36); and a rupture arrangement capable of rupturing all the partitions simultaneously (col. 25, ln 1-9; FIGS. 9, 10).

10. Claims 26-28 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(b) as being anticipated by WO 02/16545 to MINTER, et al. (hereinafter ‘Minter’).

11. As per Claim 26, Minter discloses a sampling and assay device (p. 2, second paragraph; p. 3, second paragraph) including at least three chamber portions and connected together in a row (p. 3, third paragraph; FIG. 9), each chamber portion defining a chamber, adjacent chambers along the row being separated by respective puncturable partitions (p. 2, second paragraph; p. 3, third paragraph), wherein each pair of adjacent chamber portions have respective connection portions mated together (FIG. 9), an intermediate chamber portion intermediate other chamber portions in said row has first and second connection portions, the second connection portion being capable of being mated to the first connection portion of a notional chamber portion having an identical construction to the said intermediate chamber portion (FIG. 9), whereby the sampling and assay device is capable of having further chamber portions identical to the said intermediate chamber portion connected into said row (p. 3, fourth paragraph).

12. As per Claim 27, Minter discloses a system for assembling sampling and assay devices (p. 2, second paragraph; p. 3, second paragraph) having a plurality of chambers arranged in a row (p. 3, third and fourth paragraphs; FIG. 9), the system comprising: at least one type of end chamber portion defining a chamber and having a connection portion (p. 2, second paragraph; FIG. 9); at least one type of intermediate

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chamber portion defining a chamber and having two connection portions (FIG. 9), wherein the connection portions of the types of end chamber portion and intermediate chamber portion are capable of being mated together to assemble a sampling and assay device with an end chamber portion, at least one intermediate chamber portion and a further end chamber portion connected in a row (FIG. 9).

13. As per Claim 28, Minter discloses a system according to claim 27, wherein the system includes a type of intermediate chamber portion each have a first and second connection portions, the first connection portion of one intermediate chamber portion being capable of being mated to the second connection portion of another intermediate chamber portion (p. 3, fourth paragraph; FIG. 9).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 2-8 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir in view of Minter.

17. As per Claim 2, Muir teaches a sampling and assay device comprising at least three chamber portions connected together in a row and each defining a chamber (col. 2, ln 36-46; FIGS. 9, 10). Adjacent chambers along the row are separated by respective partitions (col. 5, ln 42-44). At least one of the chambers is capable of receiving a sample (col. 4, ln 25-29; col. 5, ln 35-38; col. 10, ln 3-7; col. 18, ln 4-8; col. 19, ln 38-40; col. 22, ln 55-57) and at least a further two of the chambers contains reagent (col. 2, ln 36-46; col. 19, ln 26-29; col. 22, ln 33-36). The sampling and assay device is capable of rupturing all the partitions simultaneously (col. 25, ln 1-9; FIGS. 9, 10). Muir does not teach this device wherein adjacent chamber portions along the row are relatively movable towards each other; Muir does teach a partition rupture member in some embodiments, but it is not fixed to a chamber portion (col. 25, ln 48-52; FIGS. 11, 12).

18. Minter teaches a comparable device (p. 3, third paragraph) wherein adjacent chamber portions along the row are relatively movable towards each other (p. 4, first paragraph). In respect of each pair of adjacent chamber portions, one of the adjacent chamber portions has the respective partition fixed thereto and the other of the adjacent chamber portions has a rupture member arranged to rupture the respective partition on relative movement of the adjacent chamber portions (p. 4, second paragraph), whereby the sampling and assay device is capable of rupturing all the partitions simultaneously on relative movement of the chamber portions at the ends of the row towards each

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other (FIG. 9—All partitions could rupture simultaneously, but this would probably require more coordination than the typical practitioner could muster).

19. One of skill in the art would have found the combination of a sampling and assay device comprising at least three chamber portions connected together in a row and each defining a chamber, adjacent chambers along the row being separated by respective partitions, at least one of the chambers being capable of receiving a sample, and at least a further two of the chambers containing reagent, whereby the sampling and assay device is capable of rupturing all the partitions simultaneously, as taught by Muir, with such a device wherein adjacent chamber portions along the row are relatively movable towards each another and, in respect of each pair of adjacent chamber portions, one of the adjacent chamber portions has the respective partition fixed thereto and the other of the adjacent chamber portions has a rupture member arranged to rupture the respective partition on relative movement of the adjacent chamber portions, as taught by Minter, to offer an obvious way to improve upon existing sampling and assay devices whereby the device is made capable of accommodating reactions and reagent preparation protocols in which simultaneous mixing of the contents of multiple reaction chambers is advantageous.

20. As per Claim 3, Minter further teaches such a sampling and assay device wherein each pair of adjacent chamber portions have respective connection portions mated together (FIG. 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein each pair of adjacent chamber portions have respective connection portions

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mated together, as further taught by Minter, to offer an obvious way to build a device for simultaneous mixing of the contents of multiple reaction chambers having a convenient modular design.

21. As per Claim 4, Minter further teaches such a sampling and assay device wherein, in respect of at least one pair of adjacent chamber portions, a first one of the chamber portions has a female connection portion and the other, second one of the chamber portions has a male connection portion mated with said female connection portion, said partition being fixed on said first chamber portion across the aperture in said female connection portion and said rupture member being formed by an edge of said male connection portion facing the partition (p. 11, fourth paragraph; FIGS. 5, 8). One of skill in the art would have found the combination of the sampling and assay device of Claim 3, as taught by Muir and Minter, with such a device wherein, in respect of at least one pair of adjacent chamber portions, a first one of the chamber portions has a female connection portion and the other, second one of the chamber portions has a male connection portion mated with said female connection portion, said partition being fixed on said first chamber portion across the aperture in said female connection portion and said rupture member being formed by an edge of said male connection portion facing the partition, as further taught by Minter, to offer an obvious way to build a device for simultaneous mixing of the contents of multiple reaction chambers having a convenient modular design.

22. As per Claim 5, Minter further teaches such a sampling and assay device wherein said first one of the chamber portions comprises: an annular body defining the

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chamber and having an opening at one end at least; and a cap comprising an annular wall fitted in said opening of the annular body, the annular wall being said female connection portion (p. 10, second paragraph; FIGS. 6, 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 4, as taught by Muir and Minter, with such a device wherein said first one of the chamber portions comprises: an annular body defining the chamber and having an opening at one end at least; and a cap comprising an annular wall fitted in said opening of the annular body, the annular wall being said female connection portion, as further taught by Minter, to offer an obvious way to increase the versatility of a modular mixing/reaction vessel product.

23. As per Claim 6, Minter further teaches such a sampling and assay device wherein said first one of the chamber portions is an intermediate chamber portion arranged intermediate two end chamber portions in said row, and the annular body of said first one of the chamber portions has protruding therefrom a male connection portion connected to a female connection portion of a further, adjacent chamber portion (p. 3, third paragraph; FIGS. 5, 6, 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 5, as taught by Muir and Minter, with such a device wherein said first one of the chamber portions is an intermediate chamber portion arranged intermediate two end chamber portions in said row, and the annular body of said first one of the chamber portions has protruding therefrom a male connection portion connected to a female connection portion of a further, adjacent chamber portion, as further taught by Minter, to offer an obvious way to extend the

usefulness of the product to include reaction schemes that require separate long term storage of multiple reagents prior to use.

24. As per Claim 7, Minter further teaches such a sampling and assay device wherein the male connection portion of said first one of the chamber portions is identical to the male connection portion of said further, adjacent chamber portion (FIG. 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 6, as taught by Muir and Minter, with such a device wherein the male connection portion of said first one of the chamber portions is identical to the male connection portion of said further, adjacent chamber portion, as further taught by Minter, to offer an obvious way to create a modular product having the convenience of interchangeable parts.

25. As per Claim 8, Minter further teaches such a sampling and assay device wherein an intermediate chamber portion intermediate other chamber portions in said row has first and second connection portions, the second connection portion being capable of being mated to the first connection portion of a notional chamber portion having an identical construction to the said intermediate chamber portion, whereby the sampling and assay device is capable of having further chamber portions identical to the said intermediate chamber portion connected into said row (p. 3, fourth paragraph; FIG. 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 3, as taught by Muir and Minter, with such a device wherein an intermediate chamber portion intermediate other chamber portions in said row has first and second connection portions, the second connection portion being capable of being

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mated to the first connection portion of a notional chamber portion having an identical construction to the said intermediate chamber portion, whereby the sampling and assay device is capable of having further chamber portions identical to the said intermediate chamber portion connected into said row, as further taught by Minter, to offer an obvious way to create a modular product having the convenience of interchangeable parts.

26. As per Claim 21, Minter further teaches such a sampling and assay device wherein the chamber portion at one end of the row has a stopper which is removable to allow entry of a sample to the chamber (p. 10, fifth paragraph; FIG. 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein the chamber portion at one end of the row has a stopper which is removable to allow entry of a sample to the chamber, as further taught by Minter, to offer an obvious way to provide for introduction of samples that do not unacceptably change upon brief exposure to ambient conditions.

27. As per Claim 22, Muir further teaches such a sampling and assay device wherein the chamber which is capable of receiving a sample contains a buffer (col. 28, ln 51-58). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein the chamber which is capable of receiving a sample contains a buffer, as further taught by Muir, to offer an obvious way to standardize sample pH in an assay device designed for repetitive assays.

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28. As per Claim 23, Muir further teaches such a sampling and assay device wherein at least one of the end chamber portions at the end of the row is optically transparent in at least a part thereof for inspection of the contents (col. 31, ln 10-12). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein at least one of the end chamber portions at the end of the row is optically transparent in at least a part thereof for inspection of the contents, as further taught by Muir, to offer an obvious way to build versatility in detection means into the product.

29. As per Claim 24, Minter further teaches such a sampling and assay device wherein the gap between each partition and its respective rupture member is at most 3 mm (p. 3, fifth paragraph; FIG. 8—FIG. 8 shows the gap between the rupture member and the partition to be on the order of a thickness of a wall of the vessel). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein the gap between each partition and its respective rupture member is at most 3 mm, as further taught by Minter, to offer an obvious way to structure the device in such a way that the reaction can be commenced with minimal user effort with reliable and reproducible partition rupture.

30. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muir in view of Minter, and further in view of US 5,188,615 A to HABER, et al. (hereinafter ‘Haber’)

31. As per Claim 9, neither Muir nor Minter teaches such a sampling and assay device further comprising a barrier element extending across the chamber of the one of

the adjacent chamber portions which has the partition fixed thereto to prevent passage of the ruptured partition. Haber teaches a mixing vial featuring a comparable motivation and a comparable mechanism, said mixing vial further comprising a barrier element extending across the chamber of the one of the adjacent chamber portions which has the partition fixed thereto to prevent passage of the ruptured partition (col. 6, ln 63-67; FIG. 7—Tether 88 serves as a barrier element preventing passage of plug 86). One of skill in the art would have found the modification of the sampling and assay device of Claim 2, as taught by Muir and Minter, by adding a barrier element extending across the chamber of the one of the adjacent chamber portions which has the partition fixed thereto to prevent passage of the ruptured partition, as suggested by Haber, to offer an obvious way to prevent clogging of passageways and fluid transfer devices.

32. Claims 10 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir in view of Minter, and further in view of US 6,543,645 B2 (LACOUT).

33. As per Claim 10, neither Muir nor Minter teaches a sampling and assay device further comprising a removable blocking element arranged between a pair of adjacent chamber portions to prevent relative movement between the pair of adjacent chamber portions. Lacout teaches that such blocking elements (sealing arrangements), including removable ones, are common in the art (col. 3, ln 43-56). One of skill in the art would have found the modification of the sampling and assay device of Claim 2, as taught by Muir and Minter, by adding a removable blocking element arranged between a pair of adjacent chamber portions to prevent relative movement between the pair of adjacent

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chamber portions, as taught by Lacout, to offer an obvious way to prevent accidental and premature reaction of the sample.

34. As per Claim 11, the teachings of Minter would have strongly suggested to one of skill in the art that the scheme of Claim 10 is extendable to devices comprising additional connected chambers (p. 3, third and fourth paragraphs; FIG. 9). One of skill in the art would have found the combination of the sampling and assay device of Claim 10, as taught by Muir, Minter and Lacout, with such a device wherein a further chamber portion adjacent the pair of adjacent chamber portions has a member engaging the removable blocking element to prevent relative movement between the pair of adjacent chamber portions and the further chamber portion, as suggested by Minter, to offer an obvious way to extend the usefulness of the device to reaction schemes requiring multiple and separately stored reagents.

35. As per Claim 12, neither Muir nor Minter teaches a sampling and assay device further comprising a removable blocking element arranged to prevent relative movement of a pair of adjacent chamber portions and a further chamber portion adjacent the pair of adjacent chamber portions. Lacout teaches that such blocking elements (sealing arrangements), including removable ones, are common in the art (col. 3, ln 43-56). The teachings of Minter would have strongly suggested to one of skill in the art that the scheme of Claim 2 is extendable to devices comprising additional connected chambers (p. 3, third and fourth paragraphs; FIG. 9). One of skill in the art would have found the modification of the sampling and assay device of Claim 2, as taught by Muir and Minter, by adding a removable blocking element arranged to prevent

relative movement of a pair of adjacent chamber portions and a further chamber portion adjacent the pair of adjacent chamber portions, as suggested by the teachings of Lacout and Minter, to offer an obvious way to prevent accidental and premature reaction of the sample and extend the usefulness of the device to reaction schemes requiring multiple and separately stored reagents.

36. As per Claim 13, one of skill in the art would have understood Lacout to have included in his description of common blocking elements (sealing arrangements) those in which the removable blocking element is formed integrally with one of the chamber portions and is detachable therefrom (col. 3, ln 43-56). One of skill in the art would have found the combination of the sampling and assay device of Claim 10, as taught by Muir, Minter and Lacout, with such a device wherein the removable blocking element is formed integrally with one of the chamber portions and is detachable therefrom, as further suggested by Lacout, to offer an obvious way to prevent accidental and premature reaction of the sample.

37. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir in view of Minter, and further in view of WO 97/23596 to GOODFIELD, et al. (hereinafter ‘Goodfield’).

38. As per Claim 15, neither Muir nor Minter teaches such a sampling and assay device wherein the chamber portion at one end of the row is a tubular body having an open end distal from the adjacent chamber portion in the row for insertion of a swab for carrying a sample. Goodfield teaches such a sampling and assay device wherein the chamber portion at one end of the row is a tubular body having an open end distal from

the adjacent chamber portion in the row for insertion of a swab for carrying a sample (p. 2, second full paragraph; FIG. 1). One of skill in the art would have found the combination of the sampling and assay device of Claim 2, as taught by Muir and Minter, with such a device wherein the chamber portion at one end of the row is a tubular body having an open end distal from the adjacent chamber portion in the row for insertion of a swab for carrying a sample, as taught by Goodfield, to offer an obvious way to introduce a biological sample to the test device in a convenient manner.

39. As per Claim 16, Goodfield further teaches such a device wherein the chamber portion adjacent the tubular body has a partition fixed thereto and tubular body has a rupture member at the end proximate to the adjacent chamber portion in the row (p. 2, second full paragraph; p. 4, third paragraph; FIG. 1). One of skill in the art would have found the combination of the sampling and assay device of Claim 15, as taught by Muir, Minter and Goodfield, with such a device wherein the chamber portion adjacent the tubular body has a partition fixed thereto and tubular body has a rupture member at the end proximate to the adjacent chamber portion in the row, as further taught by Goodfield, to offer an obvious way to mix sample components with test reagents in a convenient and rapid manner.

40. As per Claim 17, Goodfield further teaches such a device wherein the rupture member is a wall extending around an aperture capable of having a swab inserted therethrough (p. 2, second paragraph, last paragraph running onto p. 3; p. 3, first full paragraph). One of skill in the art would have found the combination of the sampling and assay device of Claim 16, as taught by Muir, Minter and Goodfield, with such a

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device wherein the rupture member is a wall extending around an aperture capable of having a swab inserted therethrough, as further taught by Goodfield, to offer an obvious way to mix sample components with test reagents in a convenient and rapid manner.

41. As per Claim 18, Goodfield further teaches such a device wherein the chamber portion adjacent the tubular body has an annular portion forming a male connection portion, and the tubular body has at the end proximate to the adjacent chamber portion in the row an annular skirt forming a female connection portion mated with said male connection portion (p. 3, second full paragraph; FIG. 1). One of skill in the art would have found the combination of the sampling and assay device of Claim 16, as taught by Muir, Minter and Goodfield, with such a device wherein the chamber portion adjacent the tubular body has an annular portion forming a male connection portion, and the tubular body has at the end proximate to the adjacent chamber portion in the row an annular skirt forming a female connection portion mated with said male connection portion, as further taught by Goodfield, to offer an obvious way to assemble a test device that would function as suggested by the art.

42. As per Claim 19, Goodfield further teaches such a device, further comprising a swab for carrying a sample mounted to a holder having a releasable engagement portion arranged, on insertion of the swab into the open end of the tubular body, to engage the tubular body with the swab held outside the chamber of the chamber portion adjacent the tubular body and, on release, to allow insertion of the swab into the chamber of the chamber portion adjacent the tubular body (p. 2, fourth full paragraph; p. 4, last paragraph; p. 5, first full paragraph; FIG. 1). One of skill in the art would have

found the combination of the sampling and assay device of Claim 15, as taught by Muir, Minter and Goodfield, with such a device further comprising a swab for carrying a sample mounted to a holder having a releasable engagement portion arranged, on insertion of the swab into the open end of the tubular body, to engage the tubular body with the swab held outside the chamber of the chamber portion adjacent the tubular body and, on release, to allow insertion of the swab into the chamber of the chamber portion adjacent the tubular body, as further taught by Goodfield, to offer an obvious way to provide for any necessary delay between the time of sample collection and the time of performing the assay.

43. As per Claim 20, Goodfield further teaches such a device wherein the releasable engagement portion comprises a catch arranged to engage the open end of the tubular body and being deflectable to release the open end of the tubular body (p. 2, fourth full paragraph; p. 5, first full paragraph; FIG. 1). One of skill in the art would have found the combination of the sampling and assay device of Claim 19, as taught by Muir, Minter and Goodfield, with such a device wherein the releasable engagement portion comprises a catch arranged to engage the open end of the tubular body and being deflectable to release the open end of the tubular body, as further taught by Goodfield, to offer an obvious way to isolate the sample in case any delay is necessary between the time of sample collection and the time of performing the assay.

44. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muir in view of Minter, in view of Lacout, and further in view of Haber.

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45. As per Claim 14, neither Muir nor Minter nor Lacout specifically teaches a sampling and assay device wherein the removable blocking element is arranged at the end of a female connection portion of one of the pair of chamber portions which is mated with a male connection portion of the other of the pair of chamber portions. Haber teaches a mixing vial having such an arrangement (FIG. 7). One of skill in the art would have found the combination of the sampling and assay device of Claim 10, as taught by Muir, Minter and Lacout, with such a device wherein the removable blocking element is arranged at the end of a female connection portion of one of the pair of chamber portions which is mated with a male connection portion of the other of the pair of chamber portions, as suggested by Haber, to offer an obvious way to prevent accidental and premature reaction of the sample with separately stored reagents.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- G. LATAIX, "Packaging Container for the Extemporaneous Preparation of Multi-Component Solutions," U.S. Pat. No. 4,067,440 A. See FIG. 3.
- S. CHEN, et al., "Sample Vessels," U.S. Pat. App. No. 2003/0049833 A1. See abstract.
- D. BERNSTEIN, "Device for Self Contained Solid Phase Immunodiffusion Assay," U.S. Pat. No. 4,770,853 A.

The Lataix patent would anticipate Claim 2 but for the fact that three chambers are not specifically disclosed. (However, Claim 1 in Lataix refers to "at least two independently formed compartments.") The Chen patent application describes a device

having similar features to applicant's invention, but it does not rely on partition rupture for the mixing of chamber contents. The Bernstein patent would anticipate Claim 1 except for a reasonable argument about the meaning of simultaneous rupture of chambers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL VAN LENTE whose telephone number is (571)270-3267. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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